

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: Boyd et al.) Confirmation No.: 9392
)
Application No.: 10/749,640) Examiner: Juliana Nancy Harvey
)
Filed: December 31, 2003) Group Art Unit: 4153
)
Title: Dynamic Spinal Stabilization System)

DECLARATION UNDER 37 C.F.R. §1.131 OF ROBERT M. RODRICK

I, Robert M. Rodrick, hereby state as follows:

1. I am Chief Patent Counsel for Spine Wave, Inc., the assignee of the present application. In that position which I have held since January 2003 I work with inventors in the development and refinement of inventions and with outside counsel in the preparation, filing and prosecution of patent applications on those inventions.
2. From a date prior to November 7, 2003, until December 31, 2003, the filing date of the present application, I worked with the named inventors and outside counsel in the preparation and revision of the patent application (internally designated as SW005) for the disclosed invention pertaining to dynamic stabilization of the spine. During this period, two applications were concurrently prepared, reviewed and revised that related to dynamic stabilization of the spine. Both applications were filed on the same day. These two applications shared common inventors who were responsible for reviewing and editing the various drafts of the applications prior to filing.
3. Prior to November 7, 2003, I received the Invention Disclosure Form included as Exhibit A to the Declaration Under 37 C.F.R. 1.131 of Lawrence M. Boyd, one of the named inventors of the present application. That Invention Disclosure Form refers to an Attachment E, which was included with the form. Attachment E is a copy of notes written on a white board during a meeting attended by me and named inventors at which the invention of the present application was discussed. The date of that meeting and the

white board notes is prior to November 7, 2003. The white board notes include the statement "DUCK BILL IN ANNULOTOMY TO PREVENT IDN IN ANNULOTOMY – SELF SEAL". The term "IDN" in this statement is the abbreviation for "Injectable Disc Nucleus", a term that was used by Spine Wave to describe an injectable biomaterial intended to simulate the properties of the natural disc in order to restore as much as possible of the natural motion of the disc. This statement was part of the discussion about using the dynamic stabilization system of the Invention Disclosure Form in conjunction with an IDN.

4. In a meeting subsequent to the meeting related to the Attachment E of the Invention Disclosure Form, but prior to November 7, 2003, the use of the dynamic stabilization system of the present application in conjunction with an IDN was again discussed. Attached as Exhibit A are my notes from that meeting with some of the inventors, including the statement, "Can use in conjunction with IDN as a means of partially stabilizing the spinal segments, without making it totally rigid." Again, the term "IDN" means "Injectable Disc Nucleus", as explained above.

5. A first draft of the present application was prepared by outside counsel prior to November 7, 2003. A revised draft was prepared by outside counsel based on comments from me and one of the inventors, Lawrence Boyd. This revised draft was sent by outside counsel to me on November 11, 2003, and I forwarded this draft to the inventors on the same day, as reflected in the e-mail thread of Exhibit B.

6. While the drafts of the application were being circulated and reviewed, Mr. Boyd was working with an outside party, pursuant to a confidentiality agreement, to evaluate fatigue strength considerations for embodiments of the dynamic stabilization system disclosed in the present application, as shown in the e-mails from Lawrence Boyd dated November 12, 2003 in Exhibit B. As reflected in Mr. Boyd's e-mail comments, fatigue resistance was an important consideration in the development of an actual reduction to practice of the invention, so action was being taken between November 7 and December 31, 2003, to address this consideration.

7. As also demonstrated in the e-mail thread of Exhibit B, the revised draft of the application "included a paragraph regarding using the invention in conjunction with disc repair" (e-mails of November 11) and that a claim had been added to cover that concept. This additional disclosure and claim was based on the conception and information provided by the inventors prior to November 7, 2003.

8. On November 12, 2003, I faxed comments from Lawrence Boyd regarding the invention to outside counsel. Exhibit C. These comments pertained to certain mechanical attributes of the invention as well as to strength and fatigue considerations for certain embodiments disclosed in the subject application.

9. On November 18, 2003, Lawrence Boyd provided extensive comments regarding the November 11 draft of the application. Exhibit D. I forwarded these comments to outside counsel, along with an article provided by Lawrence Boyd regarding dynamic stabilization. Exhibits E and F.

10. On November 25, 2003, outside counsel sent me another revised draft of the application incorporating the various comments and including a new embodiment. Exhibit G. The new draft added Figures 12-18 and associated text. I forwarded this draft to the inventors before the Thanksgiving Holiday, on November 26, 2003, as shown in the e-mail thread of Exhibit H.

11. Following the Thanksgiving Holiday, I received comments from Lawrence Boyd that I forwarded to outside counsel on December 1, 2003, as shown in Exhibit H. While the other inventors were undertaking their review of the application, Lawrence Boyd sent me an article related dynamic stabilization that I forwarded to outside counsel to review in connection with the draft of the application. Exhibit I.

12. Contemporaneously we were working on the patent application on the related dynamic stabilization invention utilizing a spinal plate. On December 17, 2003, a draft of

the application for that invention was e-mailed to me, which I subsequently passed on the inventors for review. Exhibit J.

13. A new revised draft of the present application was e-mailed to me on December 19, 2003, and immediately forwarded to the inventors, the draft incorporating the changes that I had conveyed to outside counsel. Exhibit K. On that same day the names and addresses of the inventors was conveyed to outside counsel to prepare the declaration and assignments for the application. Exhibit L. I was on vacation and out of the office during the week of Christmas (December 20-28, 2003) with limited communication with the inventors. Thus, I expected that I would not receive final approval from all the inventors until December 29. Exhibit L. I also expected that we would not be able to obtain all of the inventors' signatures on the declaration for the application, but nevertheless instructed outside counsel to file the application by December 31. Exhibit L.

14. I forwarded the latest draft of the application on the plate version of the dynamic stabilization system to the inventors on December 19, as shown in the e-mail thread of Exhibit M. One of the inventors did provide comments and corrections to that application on December 23, which I passed on to outside counsel. Exhibit M. On December 23, the same inventor also provided comments on the November 25 draft of the present application. Exhibit N.

15. On December 29 and 30 I discussed minor corrections to the application with outside counsel, which was filed by Express Mail by outside counsel on December 31, 2003.

16. All of the exhibits attached hereto are true and accurate copies. Some portions have been redacted that pertain to confidential information.

17. I believe that all of the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements have been made with the knowledge that willful false statements and the

like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the present application of any patent that may issue thereon.

Robert M. Rodrick

Robert M. Rodrick

Date: January 14, 2009

Dynamic Stabilization
(L, AC, TM, JW, BR)

Can use in conjunction with IDN as a means of partially stabilizing the
spine segments, without making it totally rigid

For design

- Establish performance criteria

Y O

Michael D. Beck

From: Robert M. Rodrick [RRodrick@spinewave.com]
Sent: Wednesday, November 12, 2003 9:16 AM
To: Michael D. Beck
Subject: FW: FW: SW-0005 DYNAMIC SPINAL STABILIZATION SYSTEM

Mike

I'll call you re this email.

Bob

-----Original Message-----

From: Larry Boyd [mailto:[Larry.Boyd@medtronic.com](mailto:)]
Sent: Wednesday, November 12, 2003 10:10 AM
To: Robert M. Rodrick
Subject: RE: FW: SW-0005 DYNAMIC SPINAL STABILIZATION SYSTEM

Bob,

The FAX should be coming across now. Here are some points I think should be clear from the FAX.

1. Fatigue resistance will be important. Many of these issues can be partially addressed with material selection, proper machining and metal finishing of the sensitive screw surface.
2. Fatigue resistance may be an issue with a flexible screw with reduced cross section. In order to maintain cross sectional area for fatigue considerations, it may be possible to increase the cross section in one plane to offset the decrease in the other plane. An additional advantage of this increased cross section is that it would prevent the surgeon from inserting the flexible portion into the pedicle so that the flexion point remains extrapedicular.
3. DyNeSys has been promoting an advantage of their system over interspinous systems (like DIAM) as its location of center of rotation vs. the normal plane of motion of the spine. The normal rotation location for the spine is in the posterior 1/3 of the disc space as shown in the figure. That said, our concept is even closer to that location than Dynesys or other intersegmental concepts.
4. One additional thought. Spinal fixation procedures performed for correction of deformity in young patients could be problematic over time due to unloading of their discs for long periods of time. It would be advantageous to use a dynamic fixation concept for such procedures. However, if the flexible segments are between vertebrae (like Dynesys), it will be difficult to maintain correction, especially in multiple planes (coronal and sagittal). With our concept, a rigid rod can be used to rotate and correct the spine in 3-dimensions (as is currently done), while allowing for some physiologic loading of the disc spaces over the long periods of time likely in these very young patients. Of course, fatigue issues will be important. But, staying below the fatigue limits for the system should be possible with design considerations and material optimization.

Hope this helps. See you next week. Regards, Larry.

Larry

it is being sent under our NDA.

131 Declaration of Robert Rodrick
Exhibit B

Thanks,

Bob

-----Original Message-----

From: Larry Boyd [mailto:larryboyd@maginot.com]
Sent: Wednesday, November 12, 2003 9:28 AM
To: Robert M. Rodrick
Subject: Re: FW: SW-0005 DYNAMIC SPINAL STABILIZATION SYSTEM

Bob,

Can I forward this to _____? I will mark every page "Confidential". I will most likely not be able to get to Toledo this year and I think this will give them a good idea of the concept for getting started on the analysis. Let me know. Larry.

At 06:16 PM 11/11/03 -0500, you wrote:

Gentlemen

Attached is a revised draft of the patent application on the dynamic stabilization system concepts described in invention disclosure SW005. The draft contains changes from Larry and me. These changes include a paragraph on page 18 regarding the use of the invention in conjunction with disc repair. Claim 30 has been added to cover this concept.

The subject application is directed to the flexible screw concepts including the reduced cross-section with the protective polymeric sleeve. As such, the inventors associated with the claims as drafted are Mark, Larry and Andy.

If anyone has any comments/changes to this draft, please let me know as soon as practicable so that we can finalize the application for filing.

As to the other concepts not included, namely the allowance of some flexibility or motion at the connecting interface of the screw and stabilizing rod/plate, we are going to consider a separate application using as much of the background of this application as possible.

Bob

-----Original Message-----

From: Michael D. Beck [mailto:mdbeck@maginot.com]

Sent: Tuesday, November 11, 2003 11:49 AM

131 Declaration of Robert Rodrick

To: Robert M. Rodrick

Exhibit B

Subject: SW-0005 DYNAMIC SPINAL STABILIZATION SYSTEM

Bob:

Attached is a redline of the new patent application showing the changes made. I made the changes the you and Larry suggested, included a paragraph regarding using the invention in conjunction with disc repair, and modified the claims somewhat in line with our conversation.

mikc



131 Declaration of Robert Rodrick
Exhibit C

Two Enterprise Dr., Suite 302
Shelton, CT 06484
Tel: (203) 944-9494
Fax: (203) 944-9493

RECEIVED

NOV 12 2003

MAGINOT, MOORE
& BOWMAN

Facsimile Transmittal

To: Mike Beck **Fax:** 317-638-2139

From: Robert Rodrick **Date:** 11/12/03

RE: Attachment **Pages:** 4

Mike:

Please see attached regarding our discussion concerning the SW 005 draft.

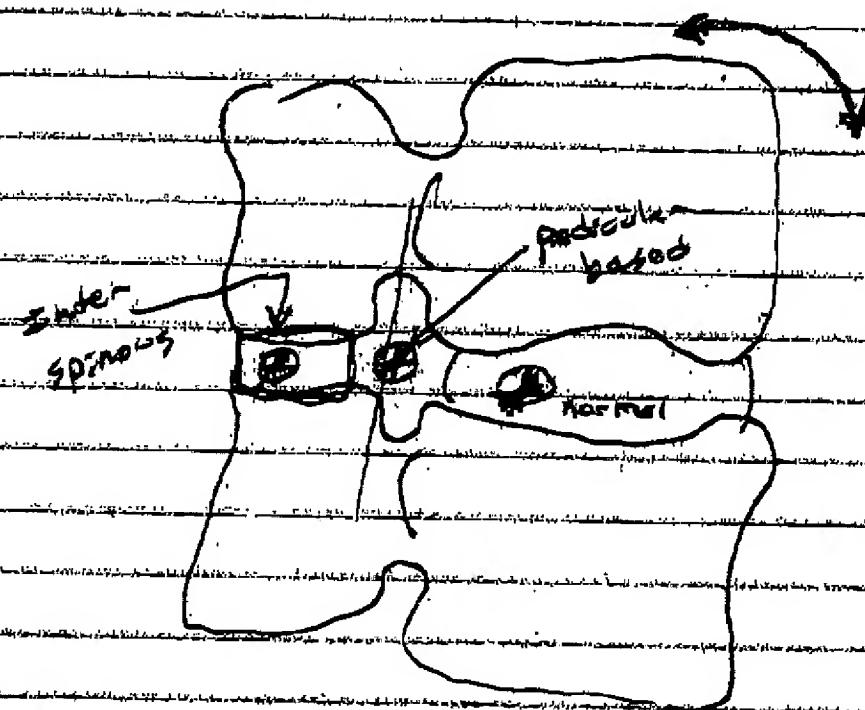
Regards,

Robert Rodrick

Center of rotation critical

5

11/10/03

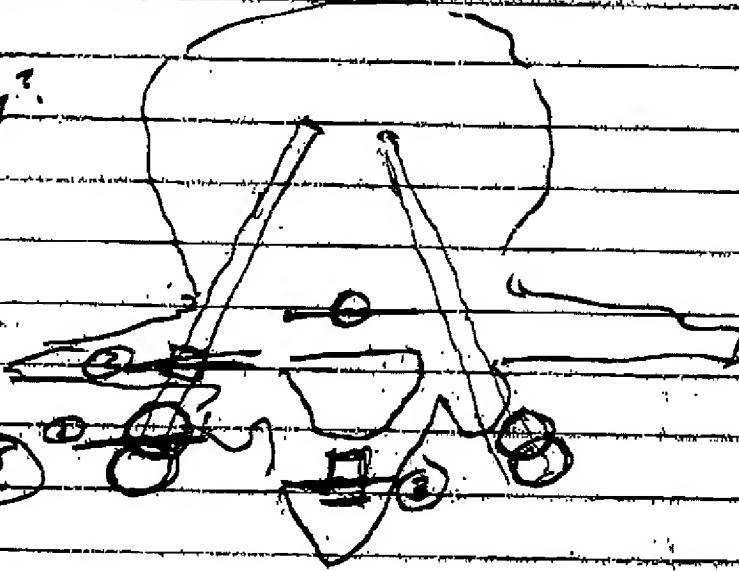


Entire spine

- Kyphotic inducing?

- Dorsal Center

- ↗ rotation



Motion location

① Dynesys

vs

② Flex Screw (closer? vs. rod location)

vs

③ PLAM for chest

→ Make entire screw flexible?

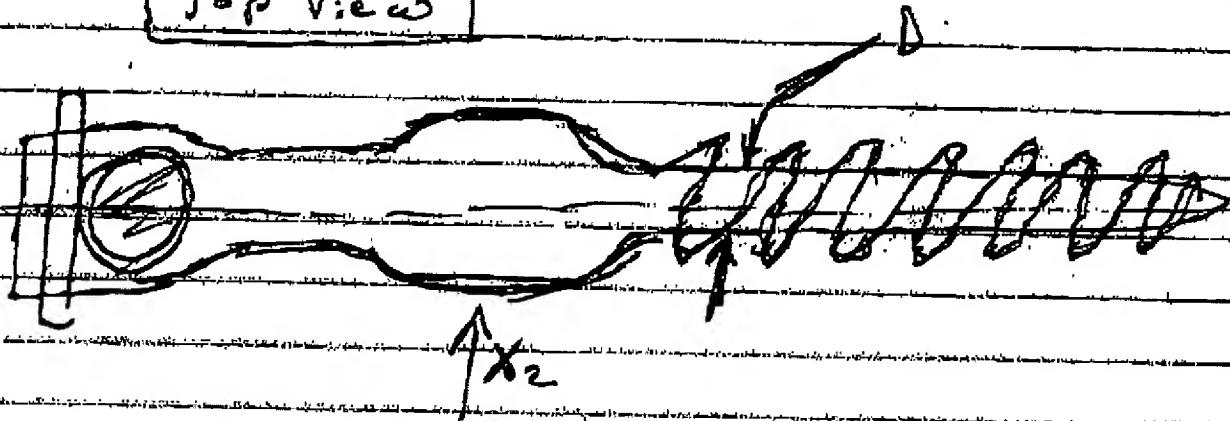
- Materials (PLA?) resorb (etc)

- Cross section flexible

over entire length or smaller

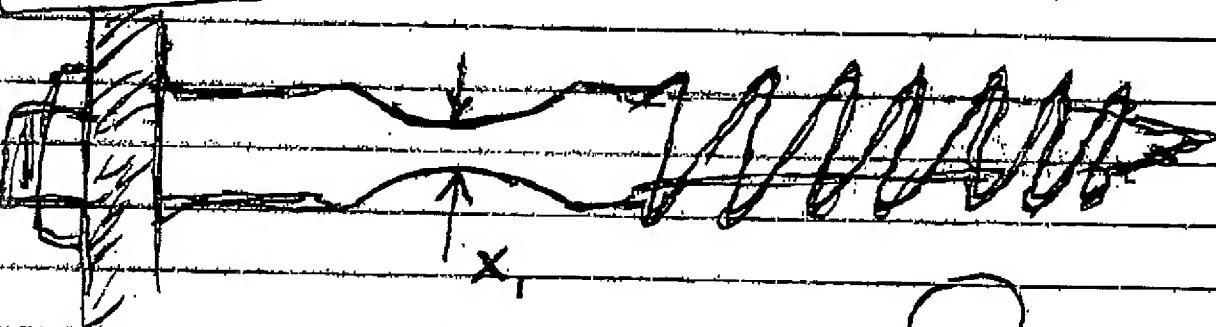
One potential solution - maintain cross-sectional area over screw length.

Top View



Add material volume to increase
Fatigue resistance and assure
Flex point is extra perpendicular

Side View



$$A = \pi \left(\frac{D}{2} \right)^2 = X_1 X_2$$

varies along l
fixed

Add x section to compensate for
stress intensity factor, K_{IC}

Block (b) possible - Uniform material

11/10/03

John B. Rodick

203 944-9493

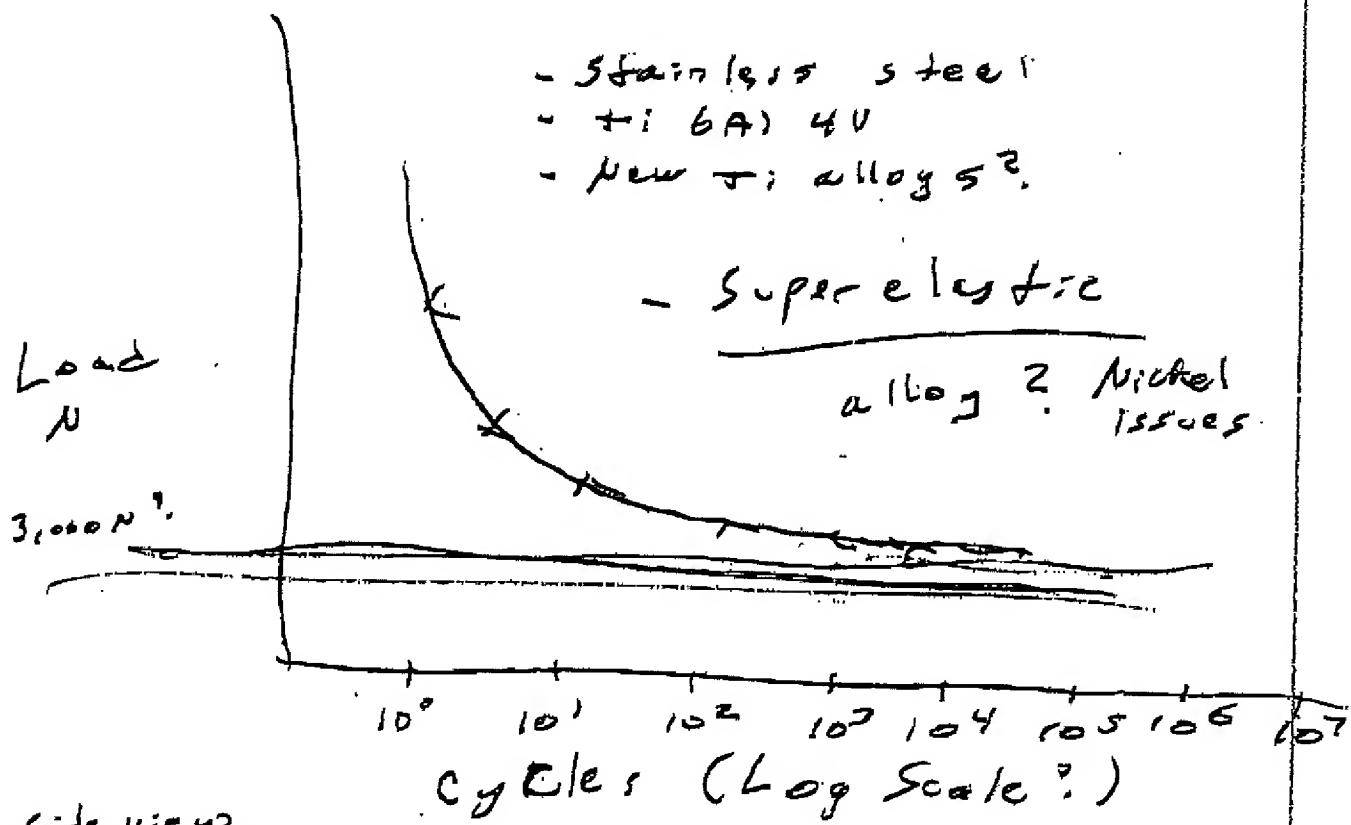
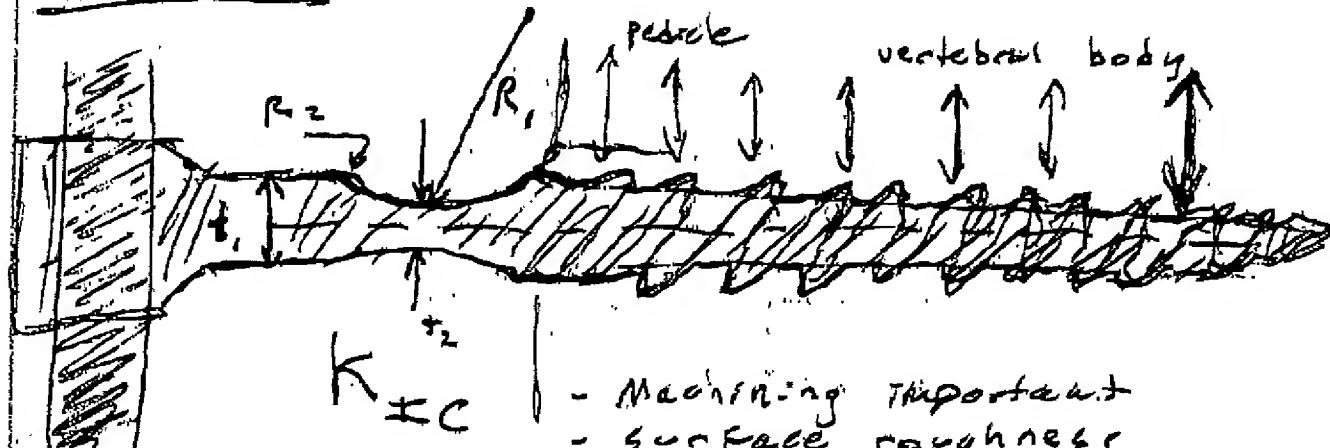
131 Declaration of Robert Rodrick
Exhibit C

Jm Bay 2 11/10/03

3

Fatigue Limit -Check Fx + fatigue text

not
Fully
reversed
(tension-
tension)

Side view

- Machining important
- Surface roughness
- Surface treatment
- polymer coating to prevent bone overgrowth

Add literature to patent application:

- 1.) Weiss Springs (Synthesis?) Attach A+B
- 2.) Modulus System (Mekanika) Attach C+D

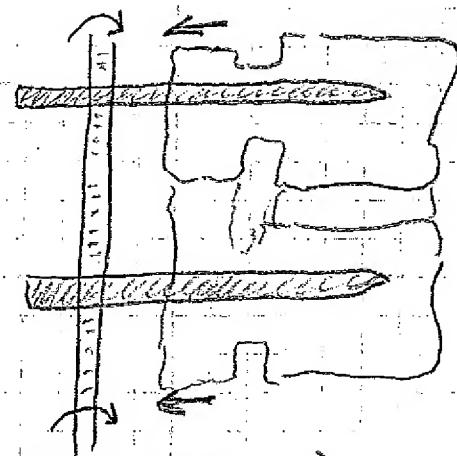
Add discussion of fatigue improvements (Attach E)

- 1.) Via material - polymers, composites, superelastic alloys (e.g. Nitinol)
- 2.) Via design - optimize radii, minimize stress concentration factors (e.g. Modified screw design. Attach F)
- 3.) Via manufacture - minimize surface roughness, pre-treat surface (e.g. Ti nitride, chrome), pre stress surface (shot peen, etc.)

Advantage of use of rigid rod for deformity correction in scoliosis, spondylosis, etc.

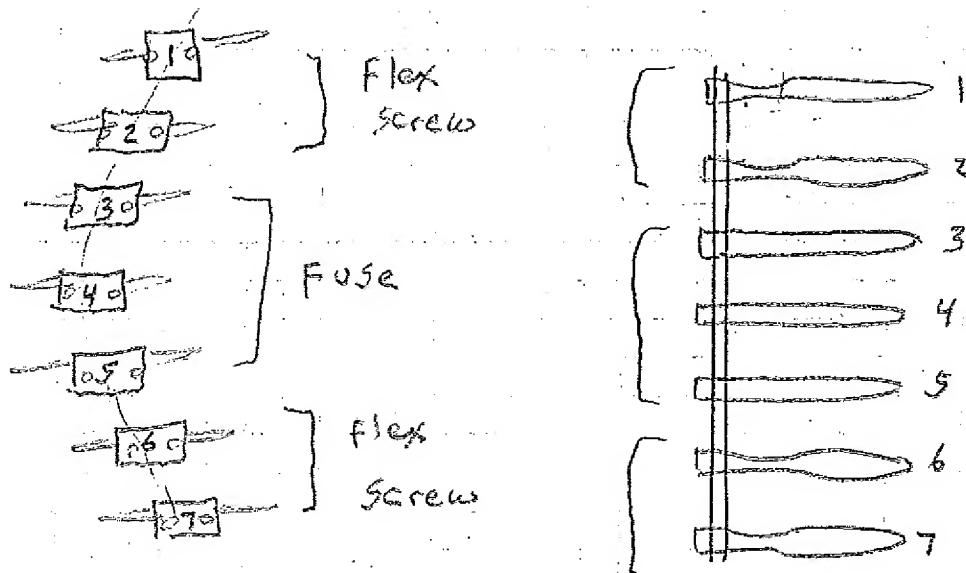
- 1.) Scoliosis - correction via rod rotation involves pulling vertebrae up to rod.

(this is not possible with a cable-based flexible system) Attachment G



During rotation,
rod reduction
brings vertebrae
up to rod.

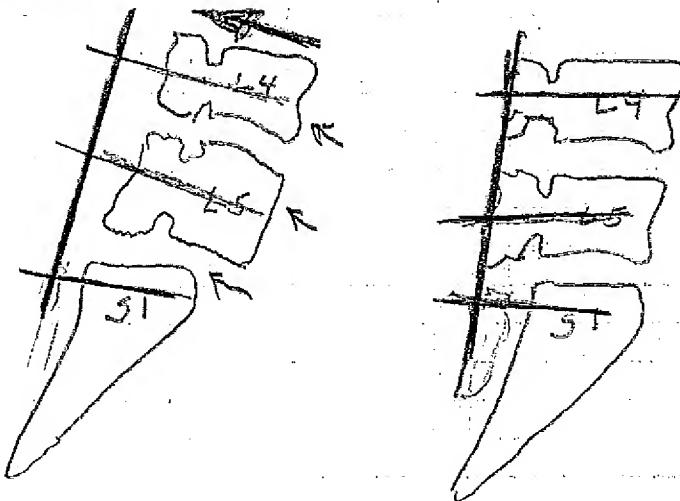
Use of a flexible system may be an advantage in scoliosis, where long rigid constructs may lead to accelerated degeneration at the distal ends (transition syndrome). It could be preferred to either use a completely non-fusion flexible screw and rod construct or to only fuse the middle segments to allow a flexible interface at the transitional segments.



Pre-op A/P

Lateral View of
Construct

2.) Spondylolisthesis - correction (needed for more severe slips - e.g., Grade 3). Via pulling vertebrae up to rod.



Obviously, a flexible cable between segments (Graf, Dynesys) provide no such capability.

Fatigue Resistance – Some Considerations

◆ Consider fatigue limit of material/design

- Material – more fatigue resistant Ti ?
- Design – radii and K_{IC} values ?
- Manufacture – surface roughness, treatment, prestress...

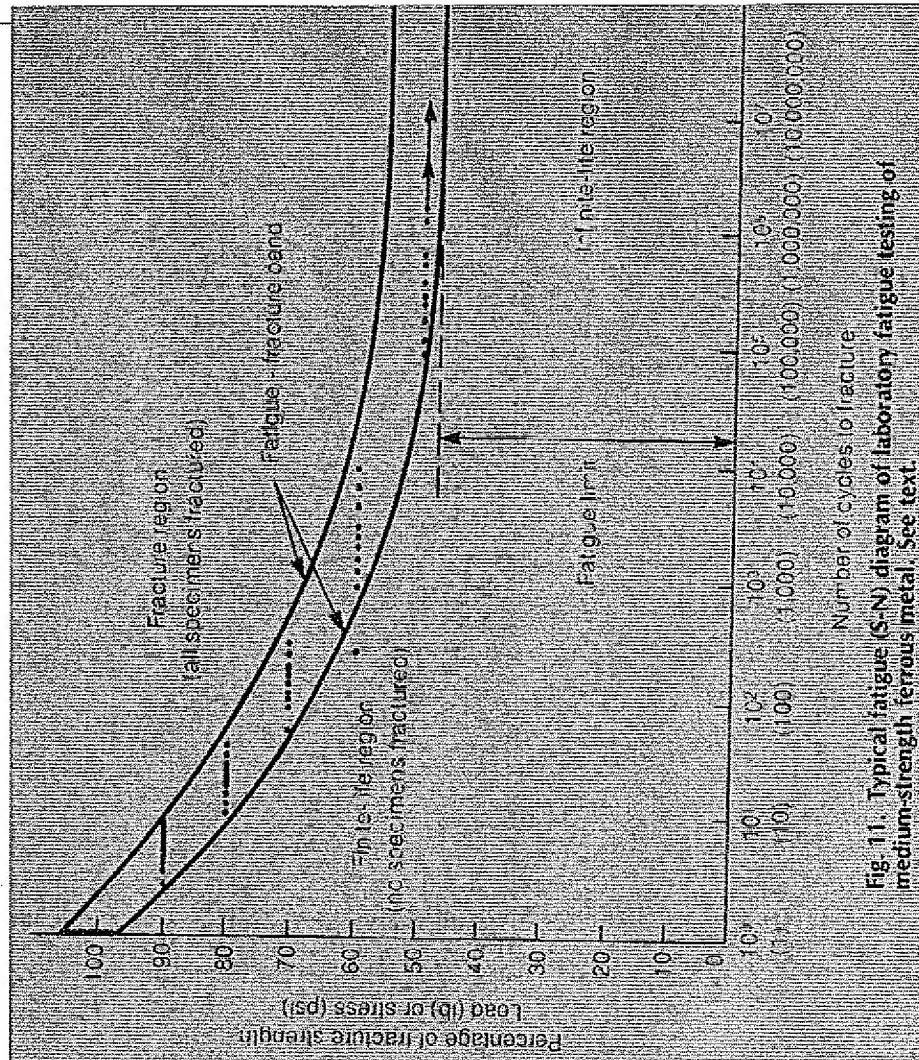
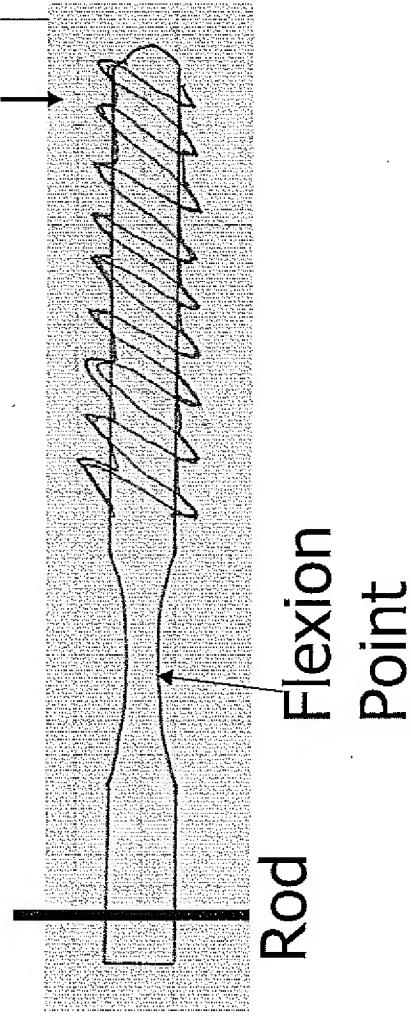


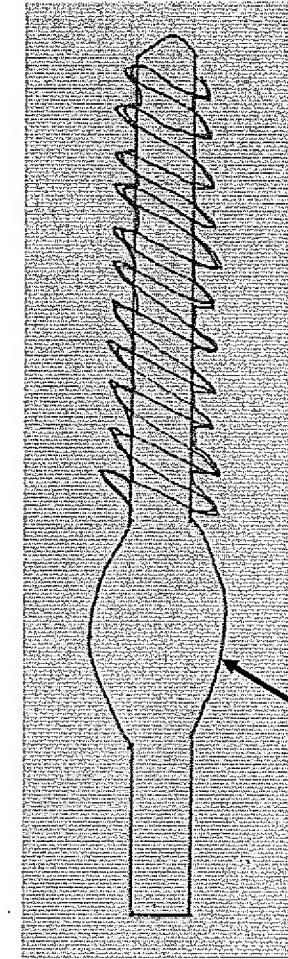
Fig 11 Typical fatigue (S-N) diagram of laboratory fatigue testing of medium strength ferrous metal. See text.

Fatigue Considerations – Screw Design

Lateral View



Top View



One possibility –
maintain material
cross-section volume
via increasing lateral
width at flexion point

Additional advantage –
assures that flexion
point is extra-
pedicular

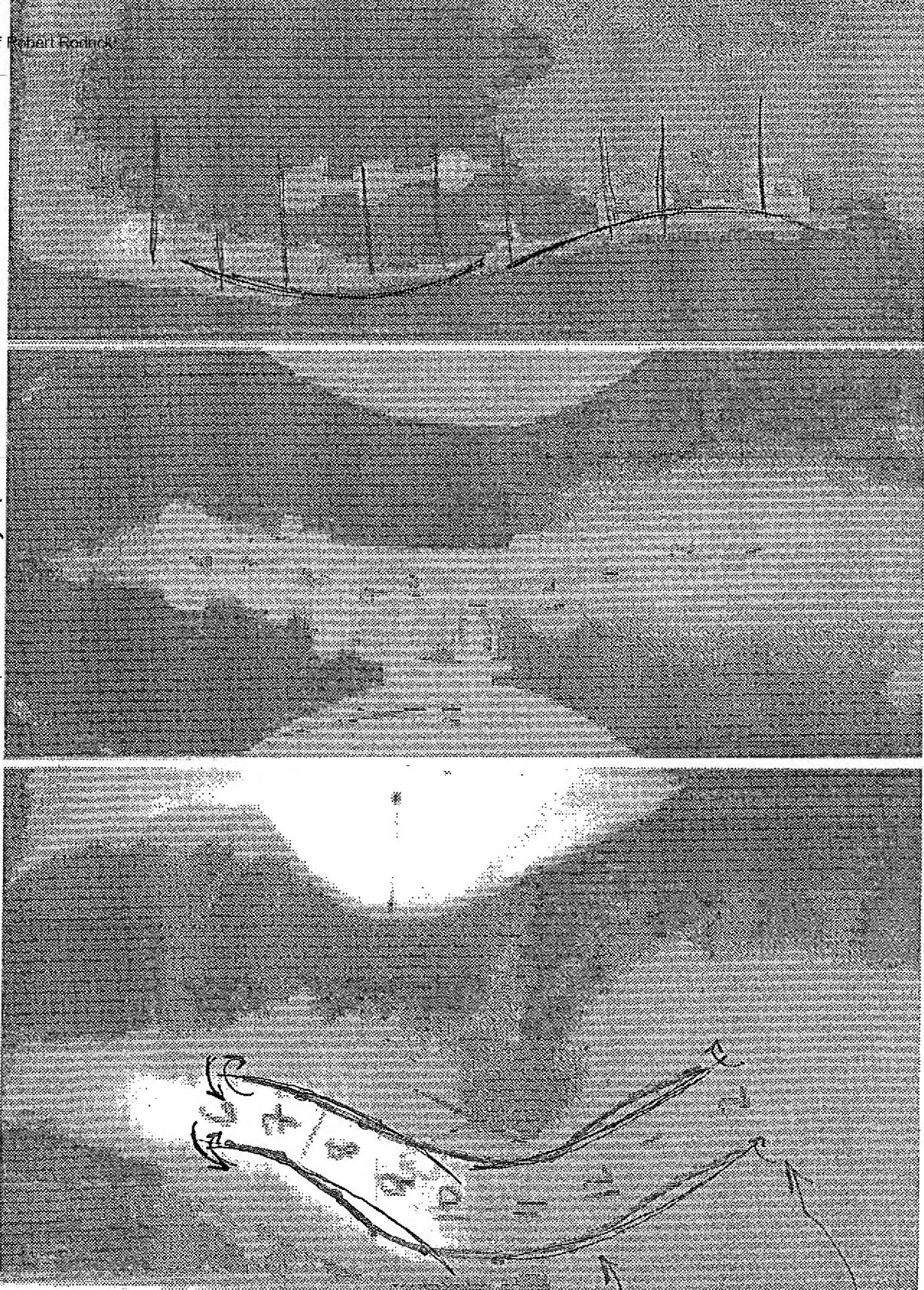
Allow uniform material
– 510(k) more likely?

Incr x-section as lateral x-section decreases

6

CIVIL SUIT

Pre-op Aff view Post-op Aff lateral

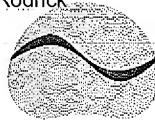


rod
atition
lane
igital

1.) Place rod
and contour
as shown.

YES

2.) Rotate
potate
and reduce



Spine Wave, Inc.

Two Enterprise Drive
Suite 302
Shelton, CT 06484

Phone: 203-944-9494
Fax: 203-944-9493

November 19, 2003

Mr. Mike Beck
Maginot, Moore & Bowman LLP
Bank One Center/Tower
111 Monument Circle, Suite 3000
Indianapolis, IN 46204-5115

Re: Invention SW005

Dear Mike:

Enclosed are copies of materials related to SW005.

Call to discuss.

Very truly yours,

Robert M. Rodrick/cln

Robert M. Rodrick
Chief Patent Counsel

RMR/cln
Enclosures

Michael D. Beck

From: Robert M. Rodrick [RRodrick@spinewave.com]
Sent: Thursday, November 20, 2003 9:54 AM
To: Michael D. Beck
Subject: FW: Electronic Version of Dynamic Stabiliz Review



Mulholland and
Sangupta 2002.p...
Mike

I sent you a hard copy of this in the recent package, but thought you might want to have an electronic version as well.

Bob

-----Original Message-----

From: Larry Boyd [mailto:larryboyd@comcast.net]
Sent: Thursday, November 20, 2003 10:02 AM
To: Jared Walkenhorst; Robert M. Rodrick; Tom Wilson; Andy Carter; Mark LoGuidice
Subject: Electronic Version of Dynamic Stabiliz Review

Here is the review article on dynamic stabilization. Its really the only article to spend any time discussing the general indications and potential mode of action of the devices. Enjoy. Regards, Larry.

Michael D. Beck

From: Michael D. Beck [mdbeck@makinot.com]
Sent: Tuesday, November 25, 2003 3:25 PM
To: 'Robert M. Rodrick'; 'Robert Rodrick'
Subject: Try this on for size

Bob:

Here is a revised draft and a new set of figures that include Tyler's embodiment.

mdb

Maginot, Moore & Beck
111 Monument Circle, Suite 3000
Indianapolis, Indiana 46204
(317) 554-2927 (direct dial)
(317) 638-2922 (office number)
(317) 638-2139 (fax)

Michael D. Beck

From: Robert M. Rodrick [RRodrick@spinewave.com]
Sent: Monday, December 01, 2003 1:22 PM
To: Michael D. Beck
Subject: FW: Dynamic Stabilization SW005

Mike

Please see Larry's comments attached. In particular, please see his question relating to the direction of the arrow on page 23.

Could you please call me tomorrow to discuss this and the status of the related second application. Also, there are a couple of other matters that I want to discuss with you when you call. Please let me know a good time for you to call. I'll be in CT all day tomorrow.

Bob

-----Original Message-----

From: Larry Boyd [mailto:larryboyd@spinewave.com]
Sent: Monday, December 01, 2003 11:22 AM
To: Robert M. Rodrick
Cc: Mark LoGuidice
Subject: Fw: Dynamic Stabilization SW005

Hi Bob,

Hope you had a good holiday. The application looks good. Here are some of my comments. Lets get it filed.
Regards, Larry

P.S. If this files before the Board Meeting, could I show an image or two to Board members? I will see what Mark thinks via CC. Mark, let me know. Maybe just a general concept picture. Larry.

X-Sieve: CMU Sieve 2.2

From: "Larry Boyd" <larryboyd@spinewave.com>
To: "Larry Boyd Duke Address" <larryboyd@spinewave.com>
Subject: Fw: Dynamic Stabilization SW005
Date: Sun, 30 Nov 2003 17:23:38 -0500
X-Mailer: Microsoft Outlook Express 6.00.2800.1158
X-Virus-Scanned: Symantec AntiVirus Scan Engine
X-PMX-Version: 4.1.0.80455

"urn:schemas-microsoft-com:office:office" xmlns:w = "urn:schemas-microsoft-com:office:word" xmlns:st1 = "urn:schemas-microsoft-com:office:smarttags">

----- Original Message -----

From: Robert Rodrick
To: 'Mark LoGuidice' ; 'Tyler Lipschultz' ; jdpafford@aol.com ; 'Larry Boyd' ; 'Andy Carter' ; 'Tom Wilson'
Cc: rrodrick@spinewave.com
Sent: Wednesday, November 26, 2003 9:01 AM
Subject: Dynamic Stabilization SW005

Gentlemen

Attached is a further draft of the subject patent application red-lined to show additional revisions. In

particular, Tyler's concepts directed to a "clothespin" flexible screw have been added (Figs 13-15) and Larry's proposed new material directed to fatigue failure and spinal deformity corrections have also been added, with changes to Figs 3, 9 and 10 and new Figs 12 and 16-18. Associated text and claims have been added.

With these revisions, the inventors are Mark, Larry, Andy and Tyler.

Please let me have any comments by the end of next week. In the meantime, a second application directed to the allowance of motion at the connecting interface of the screw and rod or plate is being prepared.

I hope you have a nice Thanksgiving.

Bob

Michael D. Beck

From: Robert M. Rodrick [RRodrick@spinewave.com]
Sent: Friday, December 05, 2003 11:43 AM
To: mdbeck@magnit.com
Subject: FW: Additional Article



Wallis System
EurSpineJ.pdf (2... Mike

Please see the attached article Larry just sent re the INV 005 application on the Flexible Screw. The article does not appear to affect our claims, but I want to be sure to include it in our IDS.

Bob

-----Original Message-----

From: Larry Boyd [mailto:
Sent: Fri 12/5/2003 12:04 PM
To: Robert M. Rodrick
Cc:
Subject: Additional Article
Hi Bob,
Found this today. Thought I would pass it along. Larry.

Michael D. Beck

From: Michael D. Beck [mdbeck@makinot.com]
Sent: Wednesday, December 17, 2003 3:16 PM
To: 'Robert M. Rodrick'
Subject: Plate version of INV-005

Bob:

The plate version of 005 is attached.

Once you guys have reviewed the case, I'll

stuff more words into the Summary.

michael

Maginot, Moore & Beck
111 Monument Circle, Suite 3000
Indianapolis, Indiana 46204
(317) 554-2927 (direct dial)
(317) 638-2922 (office number)
(317) 638-2139 (fax)

Michael D. Beck

From: Michael D. Beck [mdbeck@makinot.com]
Sent: Friday, December 19, 2003 11:09 AM
To: 'Robert Rodrick'; 'Robert M. Rodrick'
Subject: New draft

Bob:

The new draft of the application is attached with your changes incorporated. I added a few additional words about the disc prosthesis and a new claim 18. I will make similar additions to the other application once this language passes through your grist mill.

michael

Maginot, Moore & Beck
111 Monument Circle, Suite 3000
Indianapolis, Indiana 46204
(317) 554-2927 (direct dial)
(317) 638-2922 (office number)
(317) 638-2139 (fax)

Michael D. Beck

From: Robert M. Rodrick [RRodrick@spinewave.com]
Sent: Friday, December 19, 2003 5:00 PM
To: mdbeck@maganot.com
Subject: FW: New draft

Mike

Below are the full names and current addresses of the inventors for the two applications.

Bob

-----Original Message-----

From: Cathy Norton
Sent: Fri 12/19/2003 4:49 PM
To: Robert M. Rodrick
Cc:
Subject: RE: New draft
Hi Bob,

I'm Alyse.

These are the addresses you requested. Let me know if there is anything else you need. I'll see you Monday afternoon. Thanks,
Alyse

Lawrence Boyd
25 Birnham Lane
Durham, NC 27707

Andrew Carter
9R Conant Street
Acton, MA 01720

Mark D. LoGuidice
621 Warner Hill Road
Southport, CT 06890-3040

Thomas Wilson
24 Overlook Lane
Guilford, CT 06437

Tyler P. Lipschultz
6112 Avalon Drive East
New Canaan, CT 06840

John Pafford
11022 Raleigh LaGrange Road
Eads, TN 38028

-----Original Message-----

From: Robert M. Rodrick
Sent: Friday, December 19, 2003 4:37 PM
To: Michael D. Beck
Cc: Cathy Norton
Subject: RE: New draft

Mike

For the "Flexible Screw" application, the inventors are Larry Boyd, Mark LoGuidice, Andy Carter and Tyler Lipschultz.

For the "Plate" based application, the inventors are John Pafford, Tom Wilson, Mark LoGuidice and Larry Boyd.

We will likely not be able to get you the formal papers when you file these applications by the end of the year.

Cathy, would you or the temporary assistant be able to provide me with the full formal names of all these inventors and their respective addresses preferably by the end of the year so we can use the proper names when we file these applications?

Bob

-----Original Message-----

From: Michael D. Beck [mailto:mdbeck@magninot.com]
Sent: Fri 12/19/2003 2:41 PM
To: Robert M. Rodrick
Cc:
Subject: RE: New draft
Bob:

I need addresses for all of the various inventors. Also, just to be sure we're on the same page, can you list who you think should be in which case? Mike

-----Original Message-----

From: Robert M. Rodrick [mailto:RRodrick@spinewave.com]
Sent: Friday, December 19, 2003 12:14 PM
To: Michael D. Beck
Subject: RE: New draft

Mike

Thanks. I'll let you know by no later than the end of the day on Monday the 29th if anybody has any comments. In any event, please plan on getting the papers necessary to file both of these applications by Dec 31.

Have a great Christmas!

Bob

-----Original Message-----

From: Michael D. Beck [mailto:mdbeck@makinot.com]
Sent: Fri 12/19/2003 11:09 AM
To: 'Robert Rodrick'; Robert M. Rodrick
Cc:
Subject: New draft
Bob:

The new draft of the application is attached with your changes incorporated. I added a few additional words about the disc prosthesis and a new claim 18. I will make similar additions to the other application once this language passes through your grist mill.

michael

Maginot, Moore & Beck

111 Monument Circle, Suite 3000

Indianapolis, Indiana 46204

(317) 554-2927 (direct dial)

(317) 638-2922 (office number)

(317) 638-2139 (fax)

Michael D. Beck

From: Robert Rodrick [rrodrick@patmedia.net]
Sent: Tuesday, December 23, 2003 4:23 PM
To: 'Michael D. Beck'
Subject: FW: Plate version of INV-005



1842-0029 pat app
DYNAMIC SPIN... Mike

Please see comments on the attached from Andy Carter. Following this email will be another from Andy with similar comments on the first application on the flexible screw. I would like to go over these with you on Monday, Dec 29 when I get in the CT office.
Have a Merry Christmas!

Bob

-----Original Message-----

From: Andy Carter [mailto:ACarter@spinewave.com]
Sent: Tuesday, December 23, 2003 2:26 PM
To: Robert Rodrick; JPafford (AOL); Tom Wilson; Mark LoGuidice; lmb13@acpub.duke.edu
Cc: Tyler Lipschultz; Robert M. Rodrick
Subject: RE: Plate version of INV-005

I have made some comments / corrections.

Andy

-----Original Message-----

From: Robert Rodrick [mailto:
Sent: Friday, December 19, 2003 11:43 AM
To: JPafford (AOL); Tom Wilson; Mark LoGuidice;
Cc: Tyler Lipschultz; Andy Carter; Robert M. Rodrick
Subject: Plate version of INV-005

John, Tom, Mark and Larry

Attached is a draft of the second dynamic stabilization patent application specifically relating to motion at the interface of the screw and plate/rod. The inventors based upon the claims and the information included in the disclosure are John Pafford, Tom Wilson, Mark Loguidice and Larry Boyd. Mark and Larry are included since there are claims directed to the combination of this dynamic stabilization system in combination with disc repair/replacement, which is understood to be their contribution in both this approach as well with a flexible screw.

We expect to file this application and the application on the flexible screw on the same day in the Patent Office by December 31, 2003. Accordingly, please provide any comments or changes to me by

no later than the end of the day on Monday, December 29, 2003.

Bob

From: Robert Rodrick
Sent: Tuesday, December 23, 2003 4:25 PM
To: 'Michael D. Beck'
Subject: FW: Dynamic Stabilization SW005

Mike

Here's the other application with Andy's comments.

Bob

-----Original Message-----

From: Andy Carter [mailto:ACarter@spinewave.com]
Sent: Tuesday, December 23, 2003 2:55 PM
To: Robert Rodrick
Subject: RE: Dynamic Stabilization SW005

Bob,

I may be too late on this – I'm not sure what happened to my system! I have made some minor modifications to page 22 which relate to descriptions of the disc and disc nucleus replacements.

Andy

-----Original Message-----

From: Robert Rodrick [mailto:robert@rodrick.com] [mailto:robert@rodrick.com]
Sent: Wednesday, November 26, 2003 9:02 AM
To: Mark LoGuidice; Tyler Lipschultz; JPafford (AOL); 'Larry Boyd'; Andy Carter; Tom Wilson
Cc: Robert M. Rodrick
Subject: Dynamic Stabilization SW005

Gentlemen

Attached is a further draft of the subject patent application red-lined to show additional revisions. In particular, Tyler's concepts directed to a "clothespin" flexible screw have been added (Figs 13-15) and Larry's proposed new material directed to fatigue failure and spinal deformity corrections have also been added, with changes to Figs 3, 9 and 10 and new Figs 12 and 16-18. Associated text and claims have been added.

With these revisions, the inventors are Mark, Larry, Andy and Tyler.

Please let me have any comments by the end of next week. In the meantime, a second application directed to the allowance of motion at the connecting interface of the screw and rod or plate is being prepared.

I hope you have a nice Thanksgiving.

Bob